REMARKS

I. Status of the Application

This paper responds to an Office Action (paper no. 8) mailed on July 21, 2003. The application was originally filed with 24 claims. In an amendment filed on October 25, 2002, Applicant canceled claims 8 and 13-16, and amended claims 1, 5, 9, 10, 17, 19 and 23. In a subsequent response to a Final Office Action, Applicant canceled claims 1-7, 9-12, 22 and 24, and amended claims 17-21 and 23. The present paper amends claims 17, 20, and 21. Therefore, claims 17-21 and 23 are currently under consideration in the present application. Applicant respectfully requests reconsideration of the pending claims in view of the above amendment and the following remarks.

By action taken here, Applicant in no way intends to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant expressly reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art.

II. Petition for One-Month Extension of Time

This paper responds to a Non-Final Office Action, which was mailed on July 21, 2003. The Non-Final Office Action set a shortened statutory period for reply of three-months from the mailing date of the Office Action, making any response due on or before October 21, 2003. Applicant is filing this paper on November 21, 2003, which is within the first month following expiration of the shortened statutory period for reply. Applicant therefore petitions for a one-month extension of time and encloses the requisite fee under 35 CFR 1.17(a)(1).

III. Supplemental Information Disclosure Statement

Applicant filed a supplemental information disclosure statement on November 15, 2002. Applicant has not received a copy of PTO/SB/08, which lists references cited in the supplemental information disclosure statement. Applicant respectfully requests that

the next Office Action include a copy of the PTO/SB/08 form, which has been initialed by the Examiner. The references cited in the supplemental IDS included documents cited in a search report from the European Patent Office (EPO) for a corresponding patent application filed in the EPO.

IV. Amendment of Claims 17, 20, and 21

Applicant has amended claim 17 to clarify that the recited dosage form is made by coextruding an at least partially melted central core and an outer layer, and to clarify that the co-extrudate is subsequently cooled to solidify the at least partially melted central core and outer layer. Applicant has also amended claims 20 and 21 to clarify that the co-extrudate is heated during the coextrusion process. The specification, as filed, fully supports the changes to the claims, and therefore Applicant submitd that the present amendment introduces no new matter. See, for example, the Application at page 9, lines 5-20.

V. Rejection of Claims Under 35 U.S.C. § 103(a)

The Office Action rejected claims 17-21 and 23 under 35 U.S.C. § 103(a) as being unpatentable over Newton. Applicant submits that Newton, either alone or in combination with other references cited in the case, does not teach or suggest every limitation of independent claim 17, and therefore does not render obvious the claimed invention. Applicant therefore submits that claim 17, as well as claims 18-21 and 23, which depend on claim 17, are patentable over the prior art of record.

Claim 17 recites a method of making the pharmaceutical dosage form. In the claim, the pharmaceutical dosage form comprises a central core and a diffusion-limiting sleeve or outer layer. The central core has a pair of opposite end surfaces and a peripheral surface that extends between the opposite end surfaces. The diffusion-limiting sleeve, which is impervious to water or bodily fluids, surrounds the core's peripheral surface, but leaves the ends of the core exposed. As noted above, the pharmaceutical dosage form of the present application is formed by simultaneous melt extrusion of the core and sleeve, resulting in a co-extrudate having an at least partially melted central core. The resulting

co-extrudate is subsequently cooled to solidify the at least partially melted central core and outer layer.

In contrast, Newton discloses controlled release compositions, which are prepared using a wet extrusion process (see e.g., col. 1, lines 21-25, col. 2, line 63-col. 3, line 15, and col. 5, lines 51-59). The resulting wet extrudate is then dried in an oven and coated in a fluidized bed coater (see e.g., col. 6, lines 2-14). Since the process described in Newton is substantially different than the process claimed in the present application, Applicant submits that the present application is patentable over Newton.

VI. Conclusion

In view of the foregoing, Applicant respectfully submits that all pending claims are patentable over the prior art of record. If the Examiner has any questions, Applicant requests that the Examiner telephone the undersigned.

Applicant believes that any fees associated with the filing of the present amendment have been identified in a transmittal that accompanies this paper. However, if any fees are required in connection with the filing of this paper, and such fees have not been identified in the accompanying transmittal, please charge deposit account number 23-0455.

Respectfully submitted,

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